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(54) **Apparatus for peritoneal dialysis.**

(57) An automatic apparatus for peritoneal dialysis includes a dialysate-feeding unit comprising a single container or two or more containers (11) connected in parallel, a dialysate storage unit (14) for temporarily storing dialysate removed from the dialysate-feeding unit by a pump (12), a heating unit (13) for heating the dialysate before it is injected into the patient, and a dialysate discharge unit (15, 15A) for receiving the dialysate after it has passed through the patient, all of these units being connected by transfer tubing (16) to form a fluid circuit, and a control device (20) for controlling the fluid circuit.

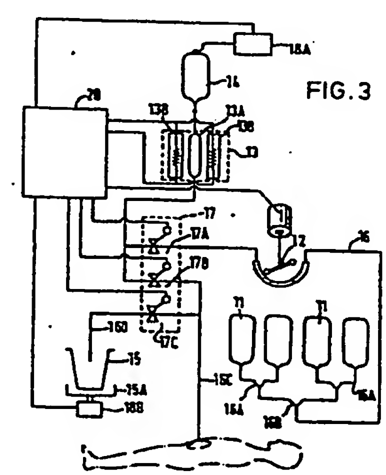


FIG.3

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# APPARATUS FOR PERITONEAL DIALYSIS

This invention relates to apparatus for peritoneal dialysis. More particularly, this invention is concerned with automatic apparatus for peritoneal dialysis which provides an essentially closed controlled fluid circuit for the dialysate.

Peritoneal dialysis is a method for removing toxic materials from the blood using the peritoneum. Recently several attempts have been made to automate peritoneal dialysis by the use of a fluid circuit. When compared with an artifical kidney, this system is easier to operate and hence has gradually gained an increased acceptance. However, conventional peritoneal dialysis systems often use a solution tank for storing the dialysate, and the fluid circuit includes a large number of circuit portions making up the circulation system, so that management of the quantity and quality of the dialysate cannot be done very conveniently.

Figure 1 illustrates a typical conventional automatic system as disclosed in Japanese Patent Publication No. JP-A-2679/1972. Referring now to Figure 1, it can be seen that the system consists of a dialysate-feeding unit 1, a constant-temperature tank 2, a dialysate transfer machine 3, a dialysate storage tank 4, a selector 5, and transfer tubing 6 connecting the members 1 to 5.

The dialysate feeding unit 1 usually consists of a single large solution tank or two or more solution bottles connected in series. A transfer tube 6A transfers dialysate from the dialysate feeding unit 1 to the constant-temperature tank 2, while a transfer tube 6B returns dialysate in excess of a predetermined injection quantity to the dialysate-feeding unit 1 from a circulation circuit. The constant-temperature tank 2 heats the dialysate to be injected into the patient to a temperature substantially equal to body temperature. Heating is effected by coiling the transfer tubing into a spiral and immersing it in a hot-water tank, or by passing hot air over the transfer tubing. The dialysate transfer machine 3 transfers a quantity of dialysate sufficient to be injected into the patient from the dialysate-feeding unit 1 to the dialysate storage tank 4. A low-speed pump or the like is used as the

transfer machine 3. The dialysate storage tank 4 stores the quantity of the dialysate for injection into the patient and consists of a container equipped with an inlet passage 6C, an outlet passage 6D, and a return passage 6E returning dialysate in excess of the predetermined quantity to the transfer machine 3. The desired predetermined quantity is decided by positioning a graduated scale on the wall and moving the end of the tube of the return passage 6E to an appropriate height. The selector 5 injects the dialysate sent from the dialysate storage tank 4 into the patient, and removes and discharges the dialysate from the patient after the passage of a predetermined period of time. For this reason, the transfer tubing 6 is formed into a T-shape within the selector 5. The first branch of the T-shaped tubing communicates with the dialysate storage tank 4, the second with the patient, and the third is for discharge. The transfer passage connected to the patient is used in common for both injection and discharge.

The critical problem with the prior art apparatus is that the dialysate frequently becomes contaminated. The possibility of contamination is greater for the tank type of dialysate-feeding unit than for the series of bottles type, but even if the dialysate-feeding unit is of the series of bottles type, contamination is likely to increase whenever the dialysate in the injection quantity is topped off. Moreover, since the circulation system is used to maintain the temperature, all the dialysate throughout the entire apparatus must be replaced at the same time in order to refresh the dialysate. Furthermore, the apparatus includes a number of portions which are exposed to the atmosphere, including the dialysate storage tank, and this results in contamination problems. Differences in osmotic pressure resulting from the different components of the dialysate have a strong influence on the condition of the patient; but in the prior-art apparatus, it has been difficult to set the osmotic pressure in the dialysate-feeding unit accurately, and to control, in practice, how much dialysate is injected into and discharged from the patient's body.

The present invention provides apparatus for peritoneal dialysis comprising a dialysate-feeding unit comprising a dialysate container or containers of the same type, a dialysate storage unit for temporarily storing dialysate removed from the dialysate-feeding unit, means for transferring dialysate from the feeding unit to the storage unit, a heater for heating the dialysate before it is injected into a patient's body; and a dialysate discharge

unit for receiving the dialysate after it has been passed through the patient's body, all of the units being connected into a controllable fluid circuit by transfer tubing, characterised in that the or each dialysate container is removably affixed, in parallel to any others, to the fluid circuit, such that the dialysate of the container or each of them can be simultaneously removed and admixed with the dialysate from any other containers at the inlet of the transfer tubing.

In the accompanying drawings:-

Figure 1, as mentioned above, is a schematic circuit diagram of a typical prior-art automatic apparatus for peritoneal dialysis;

Figure 2 is a front view of an embodiment of an automatic apparatus for peritoneal dialysis in accordance with the present invention; and

Figure 3 is a schematic circuit diagram of the apparatus shown in Figure 2.

In Figure 2, apparatus for peritoneal dialysis includes dialysate bags 11, a dialysate-feeding unit which, in this instance, is a pump 12 which pumps the dialysate from the dialysate bags 11, a heater 13, a dialysate storage bag 14 and a dialysate discharge meter 15A acting in conjunction with a dialysate discharge tank 15 to form a discharge unit. The members 11 to 15A are connected by transfer tubing 16 to form a fluid circuit. The apparatus also includes a transfer tubing switch 17 which changes the direction and branching of the circuit, and load cells 18A and 18B, which act as weighing means.

Figure 3 is a schematic circuit diagram of the construction of the apparatus described above, and is useful for explaining its function. In the present invention, the dialysate-feeding unit consists of dialysate bags 11, which are of the same size and type, positioned at the same height, and connected in parallel with one another by confluent transfer tubing 16A and 16B. The dialysate is removed from all of these bags simultaneously by the pump 12.

If a large number of dialysate bags containing dialysate of different compositions are combined as shown in Figure 3, a composite dialysate having a desired osmotic pressure suitable for the condition of the patient can be obtained by combining the several kinds of dialysates when mounting the dialysate bags 11. The osmotic pressure of the composite dialysate can be finely adjusted by replacing only one of the dialysate bags 11 in

accordance with the condition of the patient. It is also possible to use resin or glass bottles instead of bags, but in this case, the interiors of the bottles must be kept at atmospheric pressure.

The composite dialysate prepared in the manner described above is pumped by pump 12 to the transfer tubing switch 17. This switch consists of a stricture device having clamps that constrict the transfer tubing, which is flexible at at least this part of the apparatus, to cut off the communication of the fluid or to establish open communication. It is equipped with a metering clamp 17A, an injection clamp 17B, and a discharge clamp 17C, and the branching and direction of the fluid circuit are altered by instructions from a controller 20. The dialysate, which is pumped through the tubing by pump 12, passes through the metering clamp 17A and is transferred to the dialysate storage bag 14. During this time, the injection clamp 17B is kept closed. When the metering clamp 17A opens, the weight of dialysate is measured by the load cell 18A using the dialysate storage bag 14 as a metering bag, and when the weight reaches a predesired weight set in advance in the controller 20, the pump 12 is stopped by an instruction from the controller. Next, while the metering clamp 17A and the discharge clamp 17C are kept closed, the injection clamp 17B is opened so that the dialysate in the storage bag 14 is injected into the patient's body through the transfer tubing 16C by the head of pressure. In the interim, the load cell 18A continues to monitor the weight of the dialysate storage bag 14, so that its change in weight can be used as a means of monitoring the weight of fluid injected.

Finally, the injection clamp 17B is closed and the discharge clamp 17C is opened while the metering clamp 17A is kept closed, the discharge passage for the dialysate is opened, so that the dialysate flowing from inside the patient's body flows back through the transfer tubing 16C, through discharge clamp 17C and through transfer tubing 16D into dialysate discharge tank 15. A dialysate discharge meter 15A acting in conjunction with load cell 18B weighs the discharged dialysate in the same manner as that of the load cell 18A. The quantities of dialysate injected and discharged can therefore be determined by calculating the difference between the injected weight and the discharged weight. The discharge operation can be effected simultaneously with the pumping and metering operation of the dialysate into the dialysate storage tank 14.

The heater 13 consists of a heating bag 13A of a synthetic plastics material through which the dialysate flows, and two flat electric heaters 13B, 13B' of a large thermal capacity. The heating bag is preferably partitioned so that the dialysate flows through it along a zig-zag path. The flat heaters are kept at a predetermined temperature by the controller 20, and sandwich the heating bag 13A between them so as to heat the dialysate by thermal conduction. Since the apparatus of the present invention does not use hot water or the like as the heating medium, as in the conventional prior-art apparatus, the size of the dialyser as a whole can be made more compact and the control and use of the apparatus becomes much easier. Moreover, the use of this heater avoids the need for a circulation circuit for heating, and the dialysate can be kept at the optimum temperature by heating only the dialysate flowing through the heating bag 13A, both when the dialysate is being pumped into the dialysate storage unit, and when it is being injected into the human body.

The pump 12, the heater 13, and the transfer tubing switch 17 are all connected to the controller 20 by electric circuits, and the injections and discharge operations of the dialysate are under sequence control based on a timer incorporated within the controller 20. The controller 20, which is equipped with calculation means and display means, receives the values of the injections weight and discharged weight as monitored by the load cells 18A and 18B respectively, calculates the difference between those values and displays the difference on a real-time basis.

As described above, the automatic apparatus for peritoneal dialysis in accordance with the present invention enables a desired osmotic pressure of the dialysate to be selected by the combination of dialysates of differing osmotic pressures, which have previously been limited to only a few kinds of dialysates in the prior-art apparatus, and can also enable the quantity of dialysate injected into the patient to be delicately set in units of 10 grams. Moreover, temperature control can be easily effected. Since the apparatus, including the structure of the dialysate-feeding unit, the method of measuring the weight, and the position of the heating unit can all be arranged in a closed circuit, the number of connections in the transfer tubing is smaller than that in the prior apparatus, which makes the apparatus of the invention extemely hygienic.

The above described automatic apparatus of the present invention is easy for a doctor or nurse to handle, has a reduced likelihood of bacterial contamination, and can control the quality, quantity and temperature of the dialysate according to the condition of the patient.

CLAIMS

1. Apparatus for peritoneal dialysis comprising a dialysate-feeding unit comprising a dialysate container or containers of the same type, a dialysate storage unit for temporarily storing dialysate removed from the dialysate-feeding unit, means for transferring dialysate from the feeding unit to the storage unit, a heater for heating the dialysate before it is injected into a patient's body, and a dialysate discharge unit for receiving the dialysate after it has been passed through the patient's body, all of the units being connected into a controllable fluid circuit by transfer tubing, characterised in that the or each dialysate container is removably affixed, in parallel to any others, to the fluid circuit, such that the dialysate of the container or each of them can be simultaneously removed and admixed with the dialysate from any other containers at the inlet of the transfer tubing.

2. Apparatus as claimed in claim 1 characterised in that the fluid circuit is controlled by weighing means for the dialysate storage unit and the dialysate discharge unit, which are electrically connected to a calculator to calculate the quantities of dialysate injected and discharged into and from the patient from the two numerical values obtained from the weighing means, and to a display for displaying the injected and discharged quantities thus calculated.

3. Apparatus as claimed in claim 2 characterised in that the fluid circuit contains a transfer tubing switch consisting of a metering clamp, an injection clamp, and a discharge clamp, which co-operate to switch the flow of the dialysate from the storage unit, to or from the patient or to the discharge unit.

4. Apparatus as claimed in any preceding claim characterised in that the dialysate-feeding unit and/or the dialysate storage unit comprise bags suitable for holding dialysate.

5. Apparatus as claimed in any preceding claim characterised in that the heating unit comprises a synthetic resin bag provided at an intermediate portion of the fluid circuit, and heaters that sandwich the bag between them and that can heat the dialysate by thermal conduction.

6. Apparatus as claimed in any preceding claim characterised in that the heating unit and the dialysate storage unit are directly connected by a single length of transfer tubing.

FIG.1

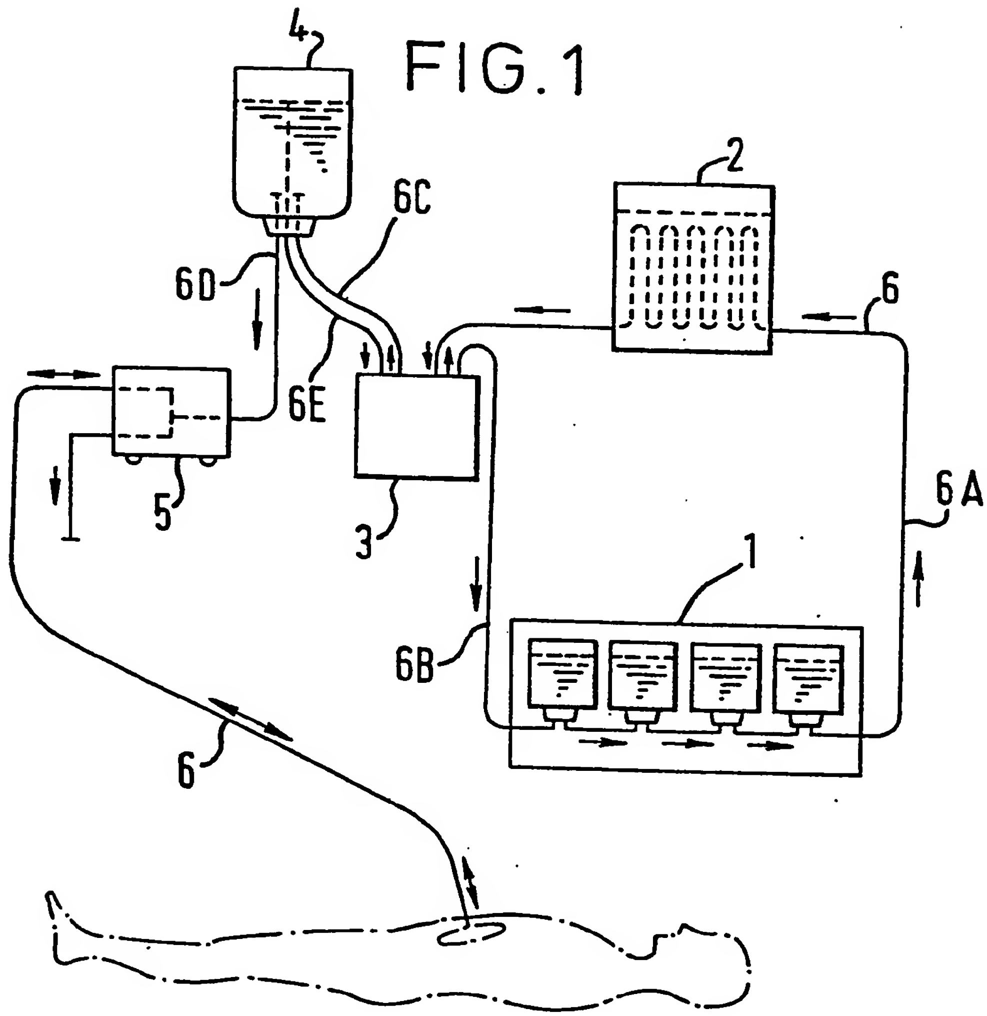
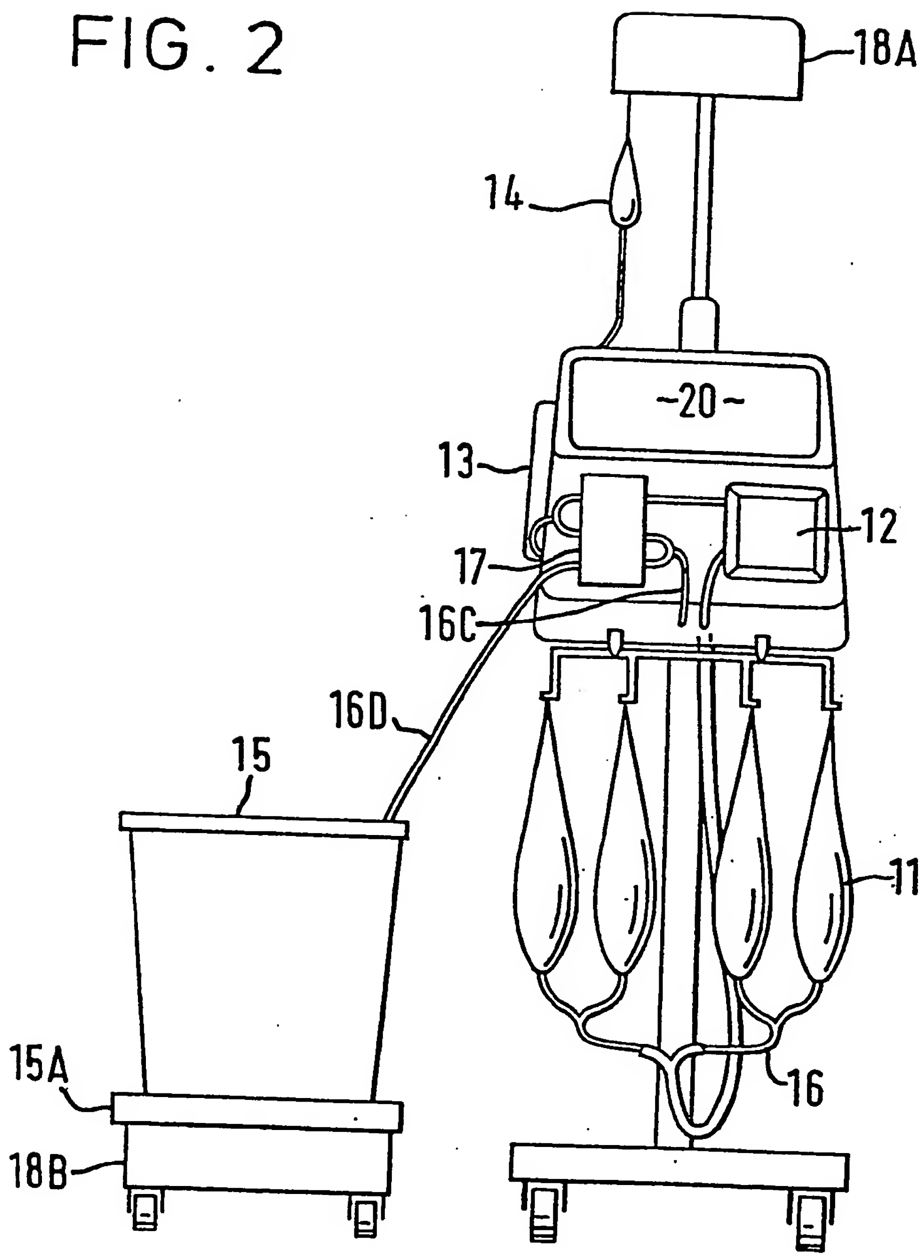


FIG. 2



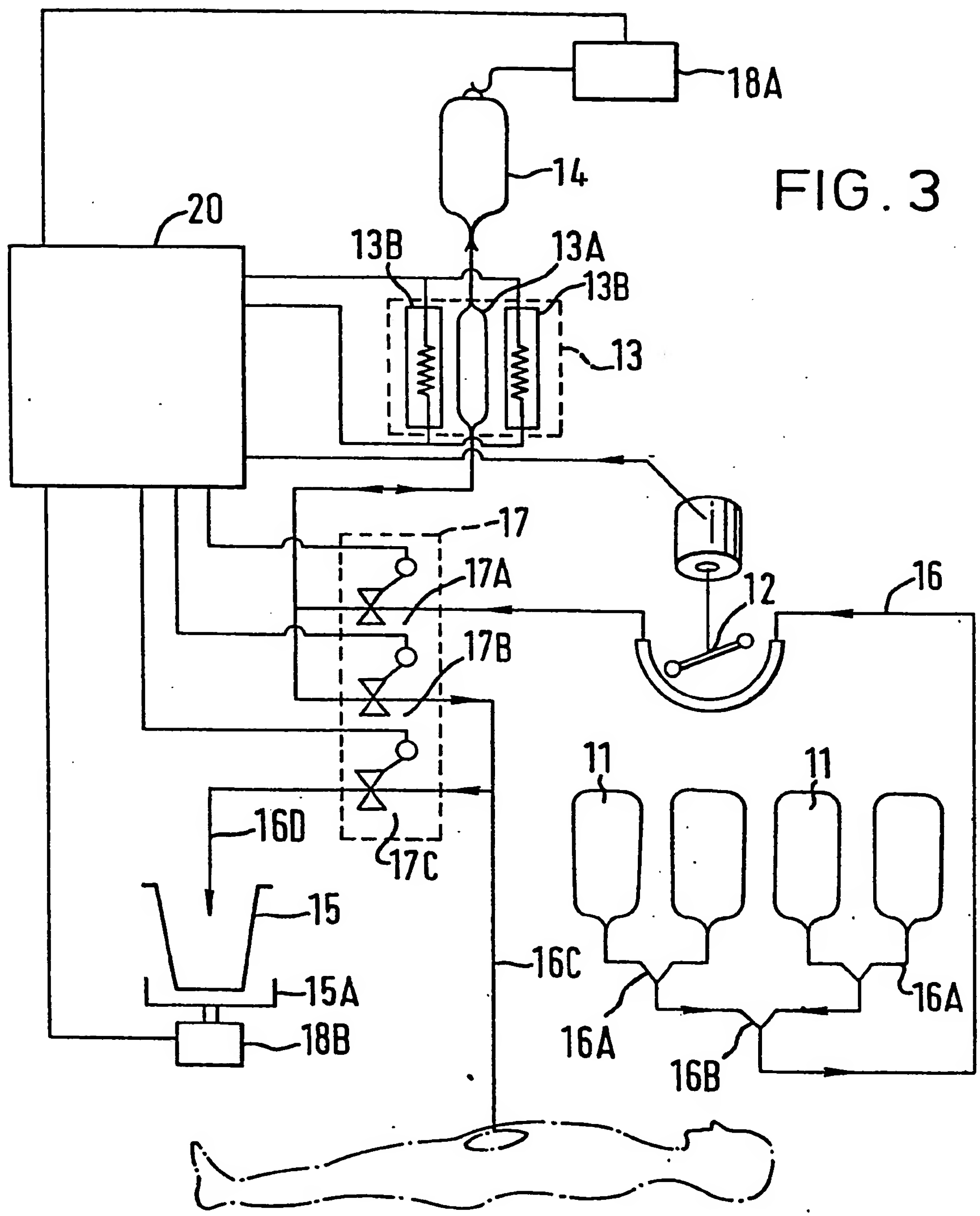

18A
14
20
13B
13A
13B
13
17
17A
12
16
17B
11
11
16D
17C
15
16C
15A
16A
16A
18B
16B

FIG. 3